2, 13-20, 23, and 29 are currently pending in the instant application. Applicants respectfully thank the Examiner for correcting the inadvertent misnumbering of the claims as filed.

Rejection under 35 U.S.C. § 112, first paragraph

The Office rejected claims 1, 13-20, 23, and 29 as allegedly nonenabled for lacking complete deposit information for the monoclonal antibodies. The deposit date, Accession number, and the complete name of the depository was included in the application as filed. In addition, for completeness, Applicants hereby amend the specification to include the current street address of the American Type Culture Collection ("ATCC").

Nonetheless, the Office has rejected the claims, asserting that the deposit is insufficient in not satisfying the Budapest Treaty. Applicants traverse because conformance with the Budapest Treaty is not necessary with this deposit. Indeed, the 11E10 and 13C4 hybridoma cell lines are known and readily available to the public, and accordingly can be made or isolated without undue experimentation. Specifically, these hybridoma cell lines are available for purchase. In support, Applicants enclose order forms printed from the ATCC on-line catalog (http://www.atcc.org) for the 11E10 and 13C4 hybridoma cell lines. Growth conditions, isotype, tissue type, and subculturing conditions are all provided in detail for these commercially available hybridomas. Applicants submit that this rejection is now moot and should be removed.

Rejection under 35 U.S.C. § 103

The Office rejected claims 1, 2, 13-20, 23, and 29 as allegedly nonobvious over Speirs et al. (*Canadian J. Microbiol.*, **37**:650-653 (1991), "Speirs") or O'Brien et al.(U.S. Pat. No.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

5,747,272, "the O'Brien patent") in view of Shitara et al. (U.S. Pat. No. 5,866,692, "Shitara"). Applicants respectfully traverse this rejection.

First, Applicants wish to note that while both the O'Brien patent and Speirs teach methods of cytotoxin detection with monoclonal antibodies, both references rely on the inventors' monoclonal antibodies (i.e., antibodies obtained from the laboratory of Dr. Alison D. O'Brien). The O'Brien patent has two inventors in common with the instant patent, and the Speirs publication notes that "the hybridoma cell lines 13C4 and 11E10 . . . were kindly provided by A. D. O'Brien."

As noted above, both the O'Brien and Speirs references discuss cytotoxin detection. Neither O'Brien nor Speirs mentions treatment of patients. The invention of Shitara is directed to treatment of cancer and to the reduction of side effects of compositions administered to humans. While Shitara correctly notes that humanization of antibodies precludes the formation of anti-mouse immunoglobulin antibody, this disclosure merely notes the benefits of humanized antibodies. It does not provide the necessary motivation to combine these references. Therefore, there would be no motivation for one of skill in the art to modify the detecting antibodies of O'Brien and Speirs according to the humanizing process of Shitara. Absent the teachings of the instant specification, Shitara does not provide any teaching that would lead one of skill in the art to adapt detection antibodies for pharmaceutical use.

Further, even assuming, *arguendo*, the existence of motivation to combine these references, one of skill in the art would still lack the reasonable expectation of success required under M.P.E.P. § 2143.02. At best, the known advantages of humanizing antibodies would lead to a motivation to try the combination. This, however, is not the standard. *Id.* Applicants alone

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

have shown that a humanized monoclonal antibody that binds to Shiga toxin protein protects mice from a lethal oral dose of toxigenic *E. coli* (see specification, pages 30-31, Tables 3 and 4). There is no teaching or suggestion in the art of record that humanized antibodies that bind to Shiga toxin would produce this result.

For the foregoing reasons, the pending claims 1, 2, 13-20, 23, and 29 satisfy the requirements of 35 U.S.C. §§ 103 and 112. Applicants respectfully request the prompt issuance of a Notice of Allowance to that effect.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Laural S. Boone
Laural S. Boone
Reg. No. 43,505

Date: October 5, 2000

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000